Stereotactic Ablative Fractionated Radiotherapy versus Radiosurgery for Oligometastatic Neoplasia to the Lung: A Randomized Phase II Trial

Shankar Siva, MD
Peter MacCallum Cancer Centre
Disclosures

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• Full author list:
Background: Why this Trial?

• The lung is the second most common place for cancer to spread

• Most patients are treated with lifelong anti-cancer drug therapy only, with little prospect for long term cancer control

• Some patients have limited spread to the lungs, and may be suitable for surgery (invasive) or Stereotactic body radiotherapy (SBRT, non-invasive)

• In this study, we evaluated two schedules of SBRT, single session and multi-session, for patients with limited secondary spread to the lung
TROG 13.01 SAFRON II: Trial Summary

Randomised phase II study (1:1; unblinded)

- Single Fraction SABR (28Gy in 1 Fraction)
- Multi Fraction SABR (48 Gy in 4 Fractions)

Stratification Factors:
- No of metastasis (1, 2 or 3)
- Histology (colorectal or non-colorectal origin)

Key Inclusion: ≤3 secondaries to the lung from any non-blood malignancy, tumor size ≤ 5cm, peripheral lung location, all primary and extrathoracic disease treated

- Primary Endpoint: Severe side effects at 1 year
- Total sample size = 90 patients over 3 years (13 centers Australia and NZ), recruited 2015-2018
Side effects (any grade) and difference between arms

Higher swallowing symptoms and skin rash with multi-session SBRT

Single session: multi session

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Primary Endpoint – high grade side effects within 1 year

• ARM 1 (single fraction) - There were two patients with grade 3 (medical intervention) events, both lasted < 3 months in duration, with no grade 4 (life threatening) or 5 (fatal) events.

• ARM 2 (four fraction) – There was one patient with a grade 5 event (pneumonitis within 3 months of SBRT, underlying ILD), with no grade 3 or 4 events.

• Grade 3+ toxicities related to treatment within 1 year
  • ARM 1 = 5% [80% CI: 1-14]
  • ARM 2 = 3% [80% CI: 0.3% - 10%]
Oncological Outcomes – Local Control

Freedom from local failure % (95% CI) at 12 months by arm

Single Fraction = 93% (79, 98)
Multi Fraction = 95% (81, 99)
Oncological Outcomes – Recurrence, Survival

Kaplan-Meier estimates % (95% CI) at 12 months by arm

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<thead>
<tr>
<th>Endpoint</th>
<th>Single Fraction</th>
<th>Multi Fraction</th>
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<td>Overall survival</td>
<td>95 (83, 99)</td>
<td>93 (80, 98)</td>
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<td>Disease free survival</td>
<td>59 (43, 72)</td>
<td>60 (44, 73)</td>
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Conclusions

• Both single fraction (28Gy) and four fraction (48Gy) SBRT have acceptable toxicity for patients with 1-3 secondary cancer deposits in the lung

• Oncological outcomes from both approaches appear similar to 1-year
IMPACT - WHAT DOES THIS MEAN?

• Single session SBRT is convenient, non-invasive safe and appears effective to date for lung secondaries

• Maybe considered a one-stop, ‘knockout punch’

• These findings may have implications for treatment selection in resource-constrained environments (such as the pandemic)